UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,599	12/12/2003	Scott A. Meyer	GUID.142PA (03-100)	1644

51294 7590 12/06/2007

HOLLINGSWORTH & FUNK, LLC
8009 34TH AVE S.
SUITE 125
MINNEAPOLIS, MN 55425

EXAMINER	
ALTER, ALYSSA M	

ART UNIT	PAPER NUMBER
3762	

MAIL DATE	DELIVERY MODE
12/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

CT

Office Action Summary	Application No.	Applicant(s)	
	10/734,599	MEYER ET AL.	
	Examiner	Art Unit	
	Alyssa M. Alter	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments filed January 25, 2007 have been fully considered but they are not persuasive. Therefore, the claims remain rejected under Schroeppel as detailed in the rejection below.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention

1. Claims 1-61 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1, 39 and 60-61 recite the limitation "indicating a cardiac response other than non-capture".

This amendment of "establish a second classification window of a trigger characteristic of the cardiac signal indicating a cardiac response *other than non-capture*" is not supported by the specification.

Additionally the amendment of "establish a second classification window of a trigger characteristic of the cardiac signal indicating a cardiac response *other than non-capture*" is a negative limitation which does not have basis in the original disclosure. Please see MPEP 2173.05(i) for further clarification.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 1-6, 8, 10-11, 13-25, 31-41, 44-49 and 51-61 stand rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Schroeppel (US 5,431,693). Schroeppel discloses that "abrupt slope changes in the second derivative are used to detect morphological features indicative of capture which are otherwise often difficult to discriminate" (col. 2, lines 56-59). "If minimum and maximum amplitude excursions of the second derivative signal occur within a selected window of time following delivery of the cardiac stimulation pulse, and if the amplitude

difference between the minimum and maximum exceeds a reference value, then capture is determined to have occurred" (col. 2-3, lines 68 and 1-6, respectively).

Schroeppel further discloses the "first window of time from about 40 msec to about 70 msec after delivery of the stimulating pulse" (col. 6, lines 43-46) and a second window from t= 70 and t=100, as seen in figure 9. "In the event that application of the method described above and illustrated in FIG. 9 results in a determination of non-capture as of the end of the first window of time at t=70, as indicated by box 108, it may nevertheless be useful to continue to look for intrinsic contractions that are manifested within that portion of the extended window of time from t=70 to t=100 ms. This can be accomplished by comparing the absolute value of the waveform amplitude A to the absolute value of Ref_2 from t=70 to t=100. If the absolute value of Ref_2 is exceeded during that time period, it will be determined that a non-capture was followed by an intrinsic contraction" (col. 8, lines 5-17). *The examiner considers the amplitude to be the morphological features.*

Since Schroeppel discloses the measurement of amplitude over the entire two windows (window one from 40-70 ms and window two from 70-100ms) in order to determine capture, the examiner considers the second classification window (70-100 ms) to be established in the event of a lack of confirmed cardiac response. Therefore, the additional window is used to confirm either capture or non capture. As such, Schroeppel discloses a "second classification window if the triggered characteristic of the cardiac signal indicating a cardiac response other than non-capture is detected in the first window".

In the alternative, although the examiner considers Schroeppel to disclose a "second classification window if the triggered characteristic of the cardiac signal indicating a cardiac response other than non-capture is detected in the first window", it would have been obvious to one having ordinary skill in the art at the time the invention was made to include an additional interval to provide the predictable result of ensuring that capture has been detected.

As to claims 4-5, 10-11 and 44-46, "this allows use of unipolar pacing between the lead tip and the pacer can without requiring a separate ring electrode for capture detection. Alternatively, bipolar pacing between the lead tip and ring electrode can be used without requiring a third electrode"(col. 5, lines 18-23).

As to claims 6, 8, 40 and 41, "the pacing/sensing electrodes 50 and 56 and corresponding conductors 48 and 54 also conduct sensed cardiac electrical signals in the right atrium and right ventricle to the atrial and ventricular sense amplifiers 40 and 42, respectively"(col. 4, lines 64-68).

As to claim 17, there is a delay between the two windows. The delay between the two windows is 0 ms, since the two windows are successive.

As to claims 21-22, "another advantage is that non-capture can be detected within 70 ms after delivery of the pacing pulse, which is early enough to permit a backup pacing pulse to be delivered immediately, if desired"(col. 5, lines 25-28).

2. Claims 7, 9 and 42-43 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Schroeppel (US 5,431,693). Schroeppel discloses the claimed invention except for delivering pacing stimulation to the left ventricle and left atrium.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the heart chambers that receive the electrical stimulation as taught by Schroeppel with the left heart chambers since it was known in the art that stimulation may be delivered to either the right or left atrium or the right or left ventricle. Such a modification would provide the predictable results of enabling the electrical stimulation system to be modified to meet specific patient needs.

3. Claim 12 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Schroeppel (US 5,431,693) in view of Zhu et al. (US 6,226,551). Schroeppel discloses the claimed invention except for using an electrode combination that reduces a pacing artifact signal relative to an evoked response. Zhu et al. teaches that it is known that "the amplitude of pacing artifact may be so great that it becomes difficult to distinguish the amplitude corresponding to an evoked response with the amplitude corresponding to artifact. Hence, there is a need for a capture verification circuit of a cardiac rhythm management device capable of differentiating between the amplitude corresponding to evoked response and the amplitude corresponding to artifact of a sensed signal."(col. 3, lines 6-14). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the pacemaker as taught by Schroeppel with the pacemaker having electrodes that reduces a pacing artifact signal relative to an evoked response as taught by Zhu et al., since such a modification would provide the predictable results and not hinder the detection of an evoked response.

4. Claims 26-30 and 50 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Schroeppel (US 5,431,693) in view of Lindgren (US 6,238,419).

Schroeppel discloses the claimed invention except for the classifying the cardiac response as a fusion/pseudoperfusion beat. Lindgren teaches that it is known to detect a fusion and/or pseudofusion heartbeat, for the purpose of enabling a reduction in the energy used for stimulating a heart. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the pacemaker as taught by Schroeppel with the pacemaker having the ability to detect fusion and/or pseudofusion heartbeat as taught by Lindgren, since such a modification would provide the predictable results of enable a reduction in the energy used for stimulating a heart in order to extend the longevity of a battery powered heart stimulation device.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571) 272-4939. The examiner can normally be reached on M-F 9am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alyssa M. Alter

Alyssa M Alter
Examiner
Art Unit 3762

GEORGE R. EVANISKO
PRIMARY EXAMINER
12/4/7